

Follow-up of the FRUIT-RCT, aspirin resistance and cardiovascular risk factors in women after recurrent hypertensive disorders of pregnancy.

Gepubliceerd: 19-03-2015 Laatste bijgewerkt: 15-05-2024

1: aspirin resistance is related to the occurrence of hypertensive disorders of pregnancy. 2: women with a history of recurrent hypertensive disorder of pregnancy develop cardiovascular risk factors more frequently than women with a history of...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24125

Bron

NTR

Verkorte titel

Follow-up FRUIT-RCT

Aandoening

Hypertensive disorders of pregnancy

Preeclampsia

Thrombophilia

Aspirin resistance

Cardiovascular risk factors

Ondersteuning

Primaire sponsor: VU University Medical Center

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Aspirin resistance and cardiovascular risk factors.

Toelichting onderzoek

Achtergrond van het onderzoek

The multicenter FRUIT-RCT demonstrated that adding low-molecular-weight heparin (LMWH) to the standard care aspirin, is beneficial in preventing early-onset hypertensive disorders of pregnancy (HD) in women with inheritable thrombophilia. Bujold et al suggested in a letter to the editor, responding to the FRUIT-RCT¹ that the effect of LMWH could have been mainly beneficial in the subgroup of women who are resistant to aspirin. To evaluate this potential relationship we perform a two stage experiment: firstly evaluation of aspirin resistance in the non-pregnant FRUIT-RCT, and secondly the evaluation of aspirin resistance during pregnancy and post-puerperium. Furthermore, we want to assess the prevalence of cardiovascular risk factors in women with inheritable thrombophilia and a history of recurrent HD. We want to examine if women with a history of recurrent hypertensive disorder of pregnancy develop cardiovascular risk factors more frequently than women with a history of single HD.

Doel van het onderzoek

1: aspirin resistance is related to the occurrence of hypertensive disorders of pregnancy.

2: women with a history of recurrent hypertensive disorder of pregnancy develop cardiovascular risk factors more frequently than women with a history of single hypertensive disorder of pregnancy.

Onderzoeksopzet

Start as soon as possible.

Onderzoeksproduct en/of interventie

Participants of the previous FRUIT-RCT receive 10 days aspirin.

For the parallel study women need to have an indication for aspirin usage in pregnancy.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion in the previous FRUIT-RCT and living in the Netherlands.

For the parallel study: indication of aspirin use during pregnancy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Diabetes Mellitus;

Drugs that are known to alter platelet function (e.g. NSAID's, tirofiban, eptifibatide, abciximab, clopidogrel, prasugrel, ticagrelor, beta-lactam antibiotics, dextran, SSRI's, clomipramine & amitriptyline, dipyridamole, verapamil, diltiazem, ginkgo biloba, ginseng, St John's wort) within 2 weeks before testing.

Major surgical procedure within one week before enrollment;

Recent cardiovascular event < 3 months

Alcohol use one day before testing aspirin resistance

Abnormal cell count.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel: Parallel

Toewijzing: Niet-gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-04-2015

Aantal proefpersonen: 128

Type: Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 19-03-2015

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41727

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4861
NTR-old	NTR5106
CCMO	NL51093.029.14
OMON	NL-OMON41727

Resultaten